Zendura® A

Safety Data Sheet (SDS)

Compliant with 29 CFR 1920.1200 Appendix D and Regulation (EC) No. 1907/2006 (REACH), Annex II

Section 1. Identification

1.1 Product identifier

Product name: Zendura® A

Other identifiers: Zendura®

1.2 Relevant identified uses of the substance and uses advised against

Recommended use: May be used as received, processed, or thermoformed to produce other articles, or as a component of other dental products

Uses advised against: No information available

1.3 Supplier details

Company name: Bay Materials

Address: 48450 Lakeview Blvd.
Fremont, CA 94538

Telephone: +1-(650)-566-0800
Email: complaints@baymaterials.com
Website: www.baymaterials.com

1.4 Emergency telephone number:

Emergency Phone Number
for Spill, Leak, Fire, Exposure, or Accident
Call INFOTRAC Day or Night
NORTH AMERICA 1-800-535-5053
INTERNATIONAL 1-352-323-3500

Section 2. Hazard(s) Identification

EMERGENCY OVERVIEW			HMIS	NFPA
Hazard Classification **According to Regulation (EC) No. 1272/2008 [CLP] and Global Harmonized System (GHS) standards**	Skin Sensitizer Category 1 acute hazards Category 3 To the aquatic environment Chronic hazards Category 3 to the aquatic environment	HEALTH	0	2
		FLAMMABILITY	1	1
		REACTIVITY	0	0
		OTHER		
Signal Word	No signal word			
Pictogram	No symbol			
Hazard Statement	H317: May cause an allergic skin reaction.			
Precautionary Statement	P261: Avoid breathing dust/fume/gas/mist/vapors/spray. P280: Wear protective gloves			

Section 3. Composition/Information on Ingredients

Component / Mixtures	CAS Number	Percentage by weight
Polyurethane	Proprietary	> 98%
Nonhazardous Ingredients	Proprietary	< 2%

Section 4. First-Aid Measures

Primary Routes of Exposure	Eyes, skin, or inhalation

Potential Health Effects

ACUTE EFFECTS

Inhalation	Inhalation of processing fumes may cause irritation to the eyes, skin, and respiratory tract. In cases of severe exposure, nausea and headache can also occur. Grease-like processing fume condensates on ventilation ductwork, molds, and other surfaces
Skin Contact	Not likely to cause irritation under normal circumstances. Skin contact with hot molten substance/product may cause thermal burns.
Eye contact	Resin particles or dust are mechanically irritating
Ingestion	Ingestion not likely due to physical form
Chronic effects	Ongoing exposure may aggravate acute effects
Carcinogenicity	See Section 11
Medical conditions aggravated by long term exposure	There are no known health effects aggravated by exposure to this product. However certain sensitive individuals or individuals with respiratory impairments may be affected by exposure to components in the processing vapors

4.1 Description of first-aid measures

Inhalation:	Remove exposed person to fresh air if adverse effects are observed.
Eye contact:	In case of contact with eyes, wash immediately with water. If easy to do, remove contact lenses. If hot melted material should splash into the eyes, flush eyes immediately with water for 15 minutes while holding the eyelids open. Immediately call a poison center or doctor.
Skin contact:	Wash skin thoroughly with soap and water. If skin irritation or rash occurs: Get medical attention. For contact with molten product, do not remove contaminated clothing. Flush skin immediately with large amounts of cold water. If possible, submerge area in cold

	water. Pack with ice. DO NOT attempt to peel polymer from skin. Seek medical attention immediately.
Ingestion:	No specific first aid measures noted. Treat symptomatically. Get medical attention.
4.2 Most important symptoms and effects, both acute and delayed:	See section 11.

4.3 Indication of any immediate medical attention and special treatment needed

Note to physician: Treat symptomatically.

Personal Protection for First-aid Responders:	When providing first aid always protect yourself against exposure to chemicals or blood borne diseases by wearing gloves, masks and eye protection. After providing first aid wash your exposed skin with soap and water.

Section 5. Fire-Fighting Measure

	General fire hazards:	**No unusual fire or explosion hazards noted.**
5.1	**Extinguishing media**	
	Suitable extinguishing media:	Use water spray, dry chemical or foam for extinction. CO_2 may be ineffective on large fires.
	Unsuitable extinguishing media:	Not determined.
5.2	**Specific hazard arising from the chemical:**	See section 10 for additional information.
5.3	**Advice for firefighters**	
	Special firefighting procedures:	Thermoplastic polymers can burn. Protect product from flames; maintain proper clearance when using heat devices, etc. Irritating or toxic substances will be emitted upon burning, combustion or decomposition. Large masses of molten polymer held at elevated temperatures for extended periods of time may auto-ignite.
	Special protective equipment for fire-fighters:	Full protective fire gear, MSHA/NIOSH approved or equivalent including self-containing breathing apparatus operated in the positive pressure mode with full facepiece, coat, pants, gloves and boots.

Section 6. Accidental Release Measures

6.1	**Personal precautions, protective equipment and emergency procedures:**	Use personal protection equipment. Do not touch damaged containers unless wearing appropriate protective clothing. Keep unauthorized personnel away. See Section 8 of the MSDS for Personal Protective Equipment.
6.2	**Environmental precautions:**	Avoid release to the environment. Prevent further spillage if safe to do so.
6.3	**Methods and material for containment and cleaning up:**	Contain spillage and collect free solid for or disposal.
6.4	**Reference to other sections:**	See sections 8 and 13 for additional information.

Section 7. Handling and Storage

7.1 Precautions for safe handling:
Avoid inhaling dust/fume/gas/mist/vapors/spray. Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Launder contaminated clothing before reuse. Avoid environmental contamination. Contact with heated material may cause thermal burns.

Refer to Processing Guide and/or contact your local Technical Service representative for melt processing temperature range. For most thermoplastic polyurethanes, melt processing is in the range of 177 - 232 deg. C (350 - 450 deg. F), however, some products may process at different temperatures. Heating above the maximum handling temperature can generate hazardous decomposition products (see Section 10). Review the temperature data in the “Maximum Handling Temperature” included in this section for processing temperature not to be exceeded.

Post thermal processing activities necessary to produce molded articles (such as cutting, sanding, sawing, grinding, drilling, or regrinding) may create dust or "fines." Powders, dust, and/or fines may pose a dust explosion hazard. Avoid inhaling dust.

Loading and unloading operations may cause nuisance dust to form. Electrostatic buildup may occur when pouring or transferring this product from its container. The spark produced may be sufficient to ignite vapors of flammable liquids. Always transfer product by means which avoid static buildup. Avoid pouring product directly from its container into combustible or flammable solvent.

Conduct any operations emitting fumes or vapors (including thermoforming, heat joining, cutting and or sealing of articles and clean up) under well-ventilated conditions. Avoid breathing process vapors. Do not hold product for extended periods of time at elevated temperatures or allow thick masses of hot polymer to accumulate because they can decompose emitting hazardous gases. Do not taste, swallow, or chew products. Wash thoroughly after processing. Do not store or consume food in processing areas. The major off-gasses from normal melt processing are expected to be water vapor and carbon dioxide. Other trace volatile organic components may also be emitted.

Observe good industrial hygiene practices. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid environmental contamination.

Do not steam sterilize articles made with Zendura® A. Methylene dianinline can be formed under these conditions.

7.2	**Maximum handling temperature:**	221 °C 430 °F
	Conditions for safe storage, including any incompatibilities:	Store away from incompatible materials. See section 10 for incompatible materials. Store in dry, well-ventilated place away from sources of heat and direct sunlight.
	Maximum Storage Temperature:	Not exceeding 55°C

Section 8. Exposure Controls / Personal Protection

8.1 Control parameters:

8.1.1 Occupational exposure limits: None of the components have assigned exposure limits.

Appropriate engineering controls: Thermal processing operations should be ventilated to control gases and fumes given off during processing.

Individual protection measures, such as personal protective equipment

General information: Use personal protective equipment as required.

Eye/face protection: If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection: To avoid burns from contact with molten product, use thermal insulating gloves. Suitable gloves can be recommended by the glove supplier.

Respiratory Protection: Under normal use conditions, respirator is not usually required. Use appropriate respiratory protection if exposure to dust particles, mist or vapors is likely. Cutting operations may create small particles from this product. If inhalation of particles cannot be avoided, wear a dust respirator. Consult with an industrial hygienist to determine the appropriate respiratory protection for your specific use of this material. A respiratory protection program compliant with all applicable regulations must be followed whenever workplace conditions require the use of a respirator.

Hygiene measures: Observe good industrial hygiene practices

Section 9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Appearance

Physical State:	Solid
Form:	Sheet
Color:	Colorless
Odor:	Odorless
Odor Threshold:	No data available.
pH:	No data available.
Melting Point:	No data available.
Boiling Point:	No data available.
Flash Point:	The product is combustible, but not flammable.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Upper/lower limit on flammability or explosive limits	
Flammability Limit - Upper (%):	No data available.
Flammability Limit - Lower (%):	No data available.
Vapor pressure:	No data available.
Vapor density (air=1):	No data available.
Relative density:	1.0 - 1.1 68 °F (20 °C)
Solubility(ies)	
Solubility in Water:	Insoluble in water
Solubility (other):	No data available.
Partition coefficient (n-octanol/water):	No data available.
Autoignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.
Explosive properties:	No data available.
Oxidizing properties:	No data available.
Pour Point Temperature	No data available.
Other information	

Section 10. Stability and Reactivity

10.1	**Reactivity:**	No data available.
10.2	**Chemical stability:**	Material is stable under normal conditions.
10.3	**Possibility of hazardous reactions:**	Will not occur.
10.4	**Conditions to avoid:**	Do not exceed 232 °C (450 °F) when thermoforming.
10.5	**Incompatible materials:**	None known, avoid contact with reactive chemicals.
10.6	**Hazardous decomposition products:**	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors. Nitrogen Oxides may also include isocyanates and small amounts of hydrogen cyanide.

Section 11. Toxicological Information

11.1 Information on likely routes of exposure

Inhalation: No data available.

Ingestion: No data available.
Skin contact: No data available.
Eye contact: No data available.

11.2 Information on toxicological effects

Acute Toxicity

Oral

Product: May cause irritation of the gastrointestinal tract if ingested
Not classified for acute toxicity based on available data.
Not expected to cause oral irritation based on available data.

Dermal

Product: Not classified for acute toxicity based on available data.

Inhalation

Product: Persons with sensitive airways (e.g., asthmatics) may react to vapors and fumes.

Skin corrosion/irritation:

Product: Contact with heated material may cause thermal burns.
Remarks: Not expected to be a primary skin irritant.

Serious eye damage/eye irritation:

Product: Contact with heated material may cause thermal burns.
Remarks: Not expected to cause eye irritation.

Respiratory sensitization:

Product: Remarks: Under decomposition conditions, isocyanates may be generated from this product. Isocyanates can cause skin sensitization and/or respiratory sensitization.

Skin sensitization:

Product: Remarks: Under decomposition conditions, isocyanates may be generated from this product. Isocyanates can cause skin sensitization and/or respiratory sensitization.

Specific target organ toxicity - single exposure: No data available

Aspiration hazard: No data available

Chronic Effects

Carcinogenicity: No data available
IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: No carcinogenic components identified
US. National Toxicology Program (NTP) Report on Carcinogens: No carcinogenic components identified
US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050), as amended: No carcinogenic components identified

Germ cell mutagenicity:

Product: This material has not exhibited mutagenic or genotoxic potential in laboratory tests.

Reproductive toxicity: No data available

Specific target organ toxicity - repeated exposure: No acute or subchronic systemic toxicity in laboratory tests

Section 12. Ecological Information

12.1 Ecotoxicity

Fish	No data available
Aquatic invertebrates	No data available
Toxicity to Aquatic Plants	No data available
Toxicity to soil dwelling organisms	No data available
Sediment Toxicity	No data available
Toxicity to Terrestrial Plants	No data available
Toxicity to Above-Ground Organisms	No data available
Toxicity to microorganisms	No data available

12.2 Persistence and degradability

Biodegradation	No data available

12.3 Bioaccumulative potential

Bioconcentration factor (BCF)	No data available
12.4 Mobility:	No data available
12.5 Other adverse effects:	No data available.

Section 13. Disposal Considerations

13.1 Waste disposal: Treatment, storage, transportation, and disposal must be in accordance with applicable Federal, State/Provincial, and Local regulations. Dispose of packaging or containers in accordance with local, regional, national and international regulations.

US EPA Waste Number: None

Section 14. Transport Information

DOT	Not regulated
IATA	Not regulated.
ADR	Not regulated.
INTERNATIONAL STANDARDS:	
IMDG	Not regulated.
Code of Emergency Measure:	
Domestic Standard: In compliance with domestic law.	
Environmental hazards:	Not regulated.
Special precautions for user:	No special precautions.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	None known.

The DOT shipping information in this section is based on a bulk container. Please review the accompanying shipping papers for the correct shipping descriptions based the size of the package. Shipping descriptions may vary based on mode of transport, quantities, temperature of the material, package size, and/or origin and destination. It is the responsibility of the transporting organization to follow all applicable laws, regulations and rules relating to the

transportation of the material.
During transportation, steps must be taken to prevent load shifting or materials falling, and all relating legal statutes should be obeyed. Review classification requirements before shipping materials at elevated temperatures

Section 15. Regulatory Information

15.1 Safety, health, and environmental regulations/legislation specific for the substance or mixture:

Australia (AICS)
This product contains a substance that is not listed on the Australia Inventory of Chemical Substances.

Canada (DSL/NDSL)
Requires notification in Canada. Research and development samples must comply with CEPA R&D requirements.

China (IECSC)
This product contains a substance or polymer that has been notified and is restricted to import by the notifier.

European Union (REACH)
To obtain information on the REACH compliance status of this product, please contact echa.europa.eu/support

Japan (ENCS)
All components are in compliance with the Chemical Substances Control Law of Japan.

Korea (KECL)
This product contains a substance or polymer that has been notified and is restricted to import by the notifier.

New Zealand (NZIoC)
This product requires notification before sale in New Zealand.

Philippines (PICCS)
All components are in compliance with the Philippines Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990 (R.A. 6969).

Switzerland (SWISS)
All components are in compliance with the Swiss Chemical Ordinance (ChemO).

Taiwan (TCSCA)
All components of this product are listed on the Taiwan inventory.

Turkey (KKDIK)
To obtain information on the KKDIK compliance status of this product, please e-mail REACH@SDSInquiries.com

United States (TSCA)

US Federal Regulations
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
None present or none present in regulated quantities.

TSCA Section 5(a)2 Significant New Use Rule (SNURs) (40CFR 721, Subpt E)
None present or none present in regulated quantities.

CERCLA Hazardous Substance List (40 CFR 302.4)
None present or none present in regulated quantities.

Superfund amendments and reauthorization act of 1986 (SARA)

SARA 311 Classifications
Respiratory or Skin Sensitization
SARA 302 Extremely Hazardous Substance
None present or none present in regulated quantities.
SARA 304 Emergency Release Notification
None present or none present in regulated quantities.
SARA 313 (TRI Reporting)
None present or none present in regulated quantities.

US State Regulations US. California Proposition 65

This product may contain chemical(s) known to the state of California to cause cancer and/or birth defects. Additional information can be received upon request.

The information that was used to confirm the compliance status of this product may deviate from the chemical information shown in Section 3.

Section 16. Other Information

Zendura® A Thermoformable sheet is a registered trademark of Bay Materials, LLC

Contact: complaints@baymaterials.com
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